

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, DC 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/637,459	04/18/97	MCKEE	M 4775-0023

HM32/0929

FINNEGAN HENDERSON FARABOW GARRETT &  
DUNNER  
1300 I STREET NW  
WASHINGTON DC 20005-3315

EXAMINER
FORTNER, V

ART UNIT	PAPER NUMBER
1541	

DATE MAILED: 09/29/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

08/837,459

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
--------------------	-------------	-----------------------	---------------------

EXAMINER

ART UNIT

PAPER NUMBER

10

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

**OFFICE ACTION SUMMARY**

Responsive to communication(s) filed on 8-19-98

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

Claim(s) 1-50 is/are pending in the application.

Of the above, claim(s) 1-27 + 33-50 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 28-32 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 6+10

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

BEST AVAILABLE COPY

Art Unit: 1641

## **DETAILED ACTION**

Claims 1-50 are pending, claims 28-32 are under consideration..

### ***Election/Restriction***

1. Claims 1-27 and 33-50 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected . Election was made **without** traverse in Paper No.9 .
2. Applicant's election without traverse of Group VII in Paper No. 9 is acknowledged.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).
4. The restriction requirement made in paper number 7 is deemed proper and is therefore made FINAL.

### ***Information Disclosure Statement***

5. The information disclosure statement submitted has been made of record and considered prior to first action.

Art Unit: 1641

***Claim Objections***

6. Claim 29 is objected to because of the following informalities: claim 29 recites an abbreviation, the meaning of which has not been defined in the claims, the recitation of abbreviations in the claims is permissible once the meaning of the abbreviation has been defined in the claims. Appropriate correction is requested.

***Claim Rejections - 35 U.S.C. § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 28-31 were read in light of the specification definition of anti-intimin antibodies on page 14, paragraph 3, wherein the anti-intimin antibodies are defined to be compositions of antibodies to intimin, a portion of intimin or an intimin-like protein from pathogenic or non-pathogenic bacteria, which also encompasses antibodies to invasin.

Art Unit: 1641

8. Claims 28-29, 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Louie et al (1993).

Louie et al disclose a composition comprising antibodies which are polyclonal, wherein the antisera was treated with lysates of uninduced *E. coli* to remove nonspecific antibodies directed to other *E. coli* components, wherein the antibodies were prepared against intimin from *E. coli* 0157 and show that the antibodies induced by the immunogen reacted with the surface exposed 97 kDa intimin (see figure 2, page 4088; preparation of antisera, page 4086, col. 2, third paragraph).

9. Claims 28 and 31 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by McKee, (May 1995).

McKee disclose polyclonal antibodies induced to a fusion protein encoded by *E. coli* *eaeA* gene, wherein the antibodies are directed against a fragment of the whole intimin protein which comprised 900 amino acids. Therefore, the composition disclosed comprised antibodies against intimin and was free of other antibodies specific for an intimin expressing host bacteria and clearly anticipates the instantly claimed invention.

10. Claims 28 and 31 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by McKee, Marian Little (1995, Dissertation Abstracts).

McKee disclose polyclonal antibodies induced to an affinity purified fusion protein encoded by *E. coli* *eaeA* gene. Therefore, the composition disclosed comprised antibodies against intimin and was free of other antibodies specific for an intimin expressing host bacteria and clearly anticipates the instantly claimed invention.

Art Unit: 1641

11. Claims 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by deAzavedo (CA2078716, March 22, 1994).

deAzavedo et al disclose and claim polyclonal and monoclonal antibodies to enterhemorrhagic E.coli attaching and effacing protein(intimin) and would therefore anticipate compositions comprising antibodies which comprise antibodies to intimin which are free of other antibodies for an intimin expressing host bacteria as a monoclonal antibodies are specific to a single epitope for an antigen, wherein the composition would also be free of other antibodies which are specific to EHEC. As claim 32 is a product by process claim, the antibodies of deAzavedo would also anticipate this claim, as the monoclonal antibodies of deAzavedo would have characteristics of an affinity purified antibody composition specific a single epitope which could be immobilized to a solid support to obtain a composition comprising antibodies to that epitope. Therefore, deAzavedo anticipates the instantly claimed compositions as now claimed.

12. Claims 28, 29, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Acheson et al (US Pat. 5,800,821).

Acheson et al disclose a monoclonal antibody invasin, designated 3A2-1(see description of drawings, Figure 3, column 4) and would therefore anticipate compositions comprising antibodies which comprise antibodies to invasin which are free of other antibodies for an invasin expressing host bacteria as a monoclonal antibodies are specific to a single epitope for an antigen, wherein the composition would also be free of other antibodies which are specific to EHEC. As claim 32 is a product by process claim, the antibodies of Acheson et al would also anticipate this claim, as

Art Unit: 1641

the monoclonal antibodies of Acheson et al would have characteristics of an affinity purified antibody composition specific a single epitope which could be immobilized to a solid support to obtain a composition comprising antibodies to that epitope. Therefore, Acheson et al anticipates the instantly claimed compositions as now claimed.

13. Claims 28-32 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Dougan et al (US Pat. 5,747,293).

Dougan et al disclose both polyclonal and monoclonal antibodies to intimin-like proteins of *E.coli*, wherein the monoclonal antibodies recognize particular epitopes of the intimin protein of enterhemorrhagic and enteropathogenic *E.coli* and would therefore anticipate compositions comprising antibodies which comprise antibodies to intimin which are free of other antibodies for an intimin expressing host bacteria as a monoclonal antibodies are specific to a single epitope for an antigen, wherein the composition would also be free of other antibodies which are specific to EHEC. As claim 32 is a product by process claim, the antibodies of Dougan et al would also anticipate this claim, as the monoclonal antibodies of Dougan et al would have characteristics of an affinity purified antibody composition specific a single epitope which could be immobilized to a solid support to obtain a composition comprising antibodies to that epitope (see entire patent). Therefore, Dougan et al anticipates the instantly claimed compositions as now claimed.

14. Claims 28-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Leong et al (1990).

Art Unit: 1641

Leong et al disclose 32 monoclonal antibodies to invasin of *Yersinia pseudotuberculosis* , wherein the 6 monocloaln antibodies were to the C-terminal region and blocked adhesin and the other were to other epitopes ~~not~~encompassed by the 192 amino acids of the C-terminal region and would therefore anticipate compositions comprising antibodies which are free of other antibodies for an intimin expressing host bacteria as ~~a~~ monoclonal antibodies are specific to a single epitope for an antigen, wherein the composition would also be free of other antibodies which are specific to EHEC. As claim 32 is a product by process claim, the antibodies of Leong et al would also anticipate this claim, as the monoclonal antibodies of Leong et al would have characteristics of an affinity purified antibody composition specific a single epitope which could be immobilized to a solid support to obtain a composition comprising antibodies to that epitope . Therefore, Leong et al anticipates the instantly claimed compositions as now claimed.

### *Conclusion*

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

16. **Amkraut et al (US Pat. 5,702,727)** is cited to show compositions comprising antibodies and invasin for the treatment of a host against infection.

17. **Ladd et al (US Pat. 5,759,551)** is cited to show the use of an invasin domain as an effective immune enhancer (column 3, lines 30-38).

18. **Tarr et al (Us Pat. 5,798,260)** is cited to show epithelial adhesin of *E.coli* O157:H7.

Art Unit: 1641

19.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first friday of each two week period.

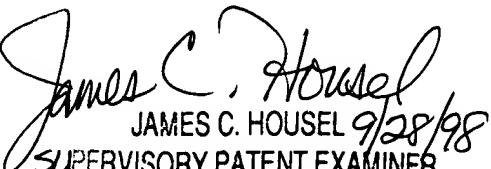
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be changing February 7, 1998. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art 1641.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

September 18, 1998

  
JAMES C. HOUSEL 9/28/98  
SUPERVISORY PATENT EXAMINER